STEERABLE CATHETER WITH REINFORCED TIP

FIELD OF THE INVENTION

The present invention relates to an improved steerable catheter having a reinforced distal end to improve deflection.

BACKGROUND OF THE INVENTION

Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

In use, the electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. Within the heart, the ability to control the exact position and orientation of the catheter tip is critical and largely determines how useful the catheter is.

Steerable (or deflectable) catheters are generally well-known. For example, U.S. Patent No. RE 34,502 describes a catheter having a control handle comprising a housing having a piston chamber at its distal end. A piston is mounted in the piston chamber and is afforded lengthwise movement. The proximal end of the catheter body is attached to the piston. A puller wire is attached to the housing and extends through the piston and through the catheter body. The distal end of the puller wire is anchored in the tip section of the catheter. In this arrangement, lengthwise movement of the piston relative to the housing results in deflection of the catheter tip section.

Often it is desirable to have a bidirectional steerable catheter, i.e., a catheter that can be deflected in two directions, typically opposing directions. For example, U.S. Patent No. 6,210,407 discloses a bidirectional steerable catheter having two puller wires extending through the catheter. The distal ends of the puller wires are anchored to opposite sides of the tip section of the catheter. A suitable bidirectional control handle is provided that permits longitudinal movement of each puller wire to thereby allow deflection of the catheter in two opposing directions.

Regardless of whether the catheter is unidirectional or bidirectional, it is typically preferred that the tip section can be deflected in the plane of the catheter so that the catheter can be more precisely controlled in the heart. However, because the tip section is generally made of a flexible material, it is sometimes difficult to limit out-of-plane deflection. Accordingly, a need

exists for a catheter having a tip section that can be consistently deflected within the plane of the catheter.

SUMMARY OF THE INVENTION

A steerable catheter having a reinforced distal end for improved deflection is provided. The catheter comprises an elongated, flexible tubular catheter body having proximal and distal ends and a lumen extending therethrough. A tip section is provided at the distal end of the catheter body. The tip section comprises a flexible plastic tubing having at least one off-axis lumen extending therethrough. A control handle is provided at the proximal end of the catheter body. At least one puller wire extends through the off-axis lumen of the tip section and lumen of the catheter body. The puller wire has a proximal end anchored to the control handle and a distal end anchored to the tip section. The puller wire is longitudinally moveable relative to the catheter body to cause deflection of the tip section in a plane in a first direction. The catheter further comprises one or more stabilizing features extending longitudinally along at least a portion of the length of the tip section and positioned generally symmetrically about a diameter of the tip section corresponding to the plane in which the tip section is deflectable. The one or more stabilizing features comprise a material that has a higher modulus of elasticity than the plastic of the tip section. The inventive catheter can be a bidirectional catheter, having two puller wires extending through opposing off-axis lumens.

DESCRIPTION OF THE DRAWINGS

These and other features of the advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of the junction of the catheter body and tip section of an embodiment of a catheter according to the invention.

FIG. 3 is a transverse cross-sectional view of the catheter body shown in FIG. 2 taken along line 3-3.

FIG. 4 is a side cross-sectional view of the distal end of the tip section shown in FIG. 2.

FIG. 5A is a transverse cross-sectional view of the tip section along line 5-5 where the tip section has two rods in the outer layer as stabilizing features.

FIG. 5B is a transverse cross-sectional view of an alternative embodiment of a tip section having two strips in the outer layer as stabilizing features.

FIG. 5C is a transverse cross-sectional view of an alternative embodiment of a tip section having two pie-shaped stabilizing features in the core.

FIG. 5D is a transverse cross-sectional view of an alternative embodiment of a tip section having a single bar-shaped stabilizing features in the core.

FIG. 6 is a transverse cross-sectional view of a catheter tip section according to the invention where the puller wires are anchored to the side walls of the tip section.

FIG. 7 is a longitudinal cross-sectional view of a preferred puller wire T-bar anchor.

FIG. 8 is a longitudinal cross-sectional view of the puller wire T-bar anchor of FIG. 7 rotated 90° to show the cross-piece on end.

DETAILED DESCRIPTION

In a particularly preferred embodiment of the invention, there is provided a steerable bidirectional electrode catheter. As shown in FIG. 1, the catheter **10** comprises an elongated catheter body **12** having proximal and distal ends, a tip section **14** at the distal end of the catheter body **12**, and a control handle **16** at the proximal end of the catheter body **12**.

As shown in FIGs. 2 and 3, the catheter body **12** comprises an elongated tubular construction having a single axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** preferably comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that when the control handle 16 is rotated the tip section **14** will rotate in a corresponding manner.

The overall length and diameter of the catheter **10** may vary according to the application. A presently preferred catheter **10** has an overall length of about 48 inches. The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french. The inner surface of the outer wall **20** is preferably lined with a stiffening tube **22**, which can be made of any suitable material, preferably nylon or polyimide. The stiffening tube **22**, along with the braided outer wall **20**, provides improved flexural and torsional stability while at the same time minimizing the wall thickness of the catheter body **12**, thus maximizing the diameter of the central lumen **18**. The outer diameter of the stiffening tube **22** is about the same as or slightly

smaller than the inner diameter of the outer wall **20**. A particularly preferred catheter **10** has an outer diameter of about 0.092 inch and a lumen **18** diameter of about 0.052 inch. If desired, the stiffening tube can be omitted.

As shown in FIG. 5A, the tip section **14** comprises a short section of flexible tubing comprising a core **24**, an inner layer **23** surrounding the core, a braided mesh **25** surrounding the inner layer, and an outer layer **27** surrounding the braid. The core **24** is formed of a suitable non-toxic plastic, preferably polyurethane or PEBAX, and has a first off-axis lumen **26** and a second off-axis lumen **28** extending therethrough. The core **24** is preferably made by extruding the plastic over two mandrels to thereby form the two off-axis lumens **26** and **28**, where the mandrels are removed after the core is extruded. The inner layer **23**, which is also made of plastic, preferably polyurethane or PEBAX, is formed over the core **24** by any suitable technique, such as extrusion, which can be performed simultaneously with the extrusion of the core.

Thereafter, the braided mesh **25** is formed over the inner layer **23**. The braided mesh **25** comprises interwoven helical members, typically twelve, sixteen or twenty-four interwoven helical members, half extending in one direction and the other half extending in the in the counter direction. The tightness or braid angle of the helical members to a line parallel with the axis of the catheter and intersecting the helical members is not critical, but is preferably about 45°. The helical members are preferably made of a conductive material having a high modulus of elasticity. Preferred helical members are made of stainless steel wire. Other methods for forming a braided mesh known in the art may be used.

Finally the outer layer **27**, which is also made of a suitable plastic such as polyurethane or PEBAX, is formed over the braided mesh **25** by any suitable technique, preferably extrusion. As would be recognized by one skilled in the art, the specific number and composition of the layers of the tip section **14** is not critical. For example, the inner layer **24** can be omitted, particularly if it is desired to have a relatively small diameter tip section. The braided mesh **25** can also be omitted, in which case the tip section **14** can optionally comprise a unitary core **24** formed without additional plastic layers. Preferably whatever design is used, the tip section **14** is more flexible than the catheter body **12**. The outer diameter of the tip section **14**, like that of the catheter body **12**, is preferably no greater than about 8 french, more preferably about 6½ french or less, but can vary depending on the particular application for which the catheter is to be used.

The off-axis lumens **26** and **28** extend through diametrically opposed halves of the tip section **14**. In the depicted embodiment, the off-axis lumens **26** and **28** are asymmetrical and therefore non-interchangeable. The first off-axis lumen **26** is smaller than the second off-axis lumen **28**. In an 8 French or 7 French diameter catheter, where the tip section is 6½ French, it is preferred that the first off-axis lumen **26** has a diameter ranging from about 0.018 inch to about 0.025 inch, more preferably from about 0.018 inch to about 0.022 inch. Preferably, the second off-axis lumen **28** has a diameter ranging from about 0.022 inch to about 0.030 inch, more preferably from about 0.026 inch to about 0.028 inch. By using two rather than three lumens along a single diameter, the present design retains the simplified construction of the unidirectional deflectable steerable catheter described in U.S. Patent No. Re 34,502, which is incorporated herein by reference. However, the number and size of the lumens in the tip section is not critical to the present invention and can vary as desired.

A preferred means for attaching the catheter body **12** to the tip section **14** is illustrated in FIG. 2. The proximal end of the tip section **14** comprises an outer circumferential notch **34** that receives the inner surface of the outer wall **20** of the catheter body **12**. The tip section **14** and catheter body **12** are attached by glue or the like. Before the tip section **14** and catheter body **12** are attached, however, the stiffening tube **22** is inserted into the catheter body **12**. The distal end of the stiffening tube **22** is fixedly attached near the distal end of the catheter body **12** by forming a glue joint with polyurethane glue or the like. Preferably a small distance, e.g., about 3 mm, is provided between the distal end of the catheter body **12** and the distal end of the stiffening tube **22** to permit room for the catheter body **12** to receive the notch **34** of the tip section **14**. A force is applied to the proximal end of the stiffening tube **22**, and, while the stiffening tube **22** is under compression, a first glue joint (not shown) is made between the stiffening tube **22** and the outer wall **20** by a fast drying glue, e.g. Super Glue®. Thereafter a second glue joint is formed between the proximal ends of the stiffening tube **22** and outer wall **20** using a slower drying but stronger glue, e.g., polyurethane. Other suitable techniques for attaching the catheter body **12** and tip section **14** can also be used in accordance with the present invention.

In the depicted embodiment, a spacer **36** lies within the catheter body **12** between the distal end of the stiffening tube **22** and the proximal end of the tip section **14**. The spacer **36** is preferably made of a material that is stiffer than the material of the tip section **14**, e.g., polyurethane, but not as stiff as the material of the stiffening tube **22**, e.g. polyimide. A spacer made of Teflon® is presently preferred. A preferred spacer **36** has a length of from about 0.25 inch to about 0.75 inch, more preferably about 0.50 inch. Preferably the spacer **36** has an outer

and inner diameter about the same as the outer and inner diameters of the stiffening tube **22**. The spacer **36** provides a transition in flexibility at the junction of the catheter body **12** and the tip section **14** to bend smoothly without folding or kinking. If desired, the spacer **36** can be omitted.

FIG. 4 provides a schematic side cross-sectional view of the tip section **14**, but does not depict the various layers described above for simplicity. As shown in FIG. 4, the distal end of the tip section **14** carries a tip electrode **38**. Mounted along the length of the tip section **14** is a ring electrode **40**. The length of the ring electrode **40** is not critical, but preferably ranges from about 1 mm to about 3 mm. Additional ring electrodes can be provided if desired. If multiple ring electrodes are used, they are spaced apart in any fashion as desired so long as their edges do not touch.

The tip electrode **38** and ring electrode **40** are each connected to a separate lead wire **30**. Each lead wire **30** extends through the second off-axis lumen **28** in the tip section **14**, through the central lumen **18** in the catheter body **12** and through the control handle **16**. The proximal end of each lead wire **30** extends out the proximal end of the control handle **16** and is connected to an appropriate connector, which can be plugged into or otherwise connected to a suitable monitor, source of energy, etc.

The lead wires **30** are connected to the tip electrode **38** and ring electrode **40** by any conventional technique. Connection of a lead wire **30** to the tip electrode **38** is preferably accomplished by solder or the like. Connection of a lead wire **30** to a ring electrode **40** is preferably accomplished by first making a small hole through the wall of the tip section **14** into the second lumen **28** through which the lead wire extends. Such a hole can be created, for example, by inserting a needle through the wall of the tip section **14** and heating the needle sufficiently to form a permanent hole. A lead wire **30** is then drawn through the hole by using a microhook or the like. The end of the lead wire **30** is then stripped of any coating and welded to the underside of the ring electrode **40**, which is then slid into position over the hole and fixed in place with polyurethane glue or the like.

Two puller wires **32** extend through the catheter **10**. Each puller wire **32** extends from the control handle **16**, through the central lumen **18** in the catheter body **12** and into one of the off-axis lumens **26** and **28** of the tip section **14**. As described in more detail below, the proximal end of each puller wire **32** is anchored within the control handle **16** and the distal end of each puller wire **32** is anchored within the tip section **14**.

Each puller wire **32** is made of any suitable metal, such as stainless steel or Nitinol. Preferably each puller wire **32** has a coating, such as a coating of Teflon® or the like. Each

puller wire **32** has a diameter preferably ranging from about 0.006 inch to about 0.0010 inch. Preferably both of the puller wires **32** have the same diameter.

Each puller wire **32** is anchored near the distal end of the tip section **14**. In the embodiment depicted in FIG. 4, the puller wires **32** are both anchored in blind holes **37** in the tip electrode **38** by a welding or the like.

Alternatively, one or both puller wires **32** can be anchored to the side wall of the tip section **14**. In the alternative embodiment of FIGs. 6 to 8, the puller wire **32** in the first off-axis lumen **26** is anchored to the side wall of the tip section **14** and attached by means of an anchor **44** fixedly attached to the distal end of the puller wire **32**. The anchor **44** is formed by a metal tube **45**, e.g., a short segment of hypodermic stock, that is fixedly attached, e.g. by crimping, to the distal end of the puller wire **32**. The tube has a section that extends a short distance beyond the distal end of the puller wire **32**. A cross-piece **47** made of a small section of stainless steel ribbon or the like is soldered or welded in a transverse arrangement to the distal end of the metal tube which is flattened during the operation. This creates a T-bar anchor **44**. A notch is created in the side of the tip section **14**, resulting in an opening in the off-axis lumen **26** carrying the puller wire **32**. The cross piece **47** lies transversely within the notch. Because the length of the ribbon forming the cross-piece **47** is longer than the diameter of the opening into the off-axis lumen **26**, the anchor **44** cannot be pulled completely into the off-axis lumen **26**. The notch is then sealed with polyurethane glue or the like to give a smooth outer surface. The glue flows into the off-axis lumen **26** to fully secure the anchor. A tunnel (not shown), in the form of polyimide tubing or the like, can be provided to permit passage of the lead wire **30** through the glue so that this same puller wire anchor construction can be used in the second off-axis lumen **28**. Other means for anchoring the puller wires **32** in the tip section **14** would be recognized by those skilled in the art and are included within the scope of the invention.

In the depicted embodiment, the distal ends of the puller wires **32** are attached to opposite sides of the tip section **14**. This design permits deflection of the tip section **14** in opposing directions. In another embodiment, the puller wires **32** can be attached at different locations along the length of the tip section **14**, i.e., with the distal end of one puller wire anchored proximal the distal end of the other puller wire. Such a design would permit deflection at different points along the length of the tip section.

The catheter **10** further comprises two compression coils **46**, each in surrounding relation to a corresponding puller wire **32**, as shown in FIGs. 2 and 3. Each compression coil **46** is made of any suitable metal, such as stainless steel. Each compression coil **46** is tightly wound on itself

to provide flexibility, i.e., bending, but to resist compression. The inner diameter of each compression coil **46** is slightly larger than the diameter of its associated puller wire **32**. For example, when a puller wire **32** has a diameter of about 0.007 inch, the corresponding compression coil **46** preferably has an inner diameter of about 0.008 inch. The coating on the puller wires **32** allows them to slide freely within the compression coil **46**. The outer surface of each compression coil **46** is covered along most of its length by a flexible, non-conductive sheath **48** to prevent contact between the compression coil **46** and the lead wires **30** within the central lumen **18**. A non-conductive sheath **48** made of thin-walled polyimide tubing is presently preferred.

At the distal end of the catheter body, the two compression coils **46** are positioned in diametric opposition within the stiffening tube **22** and spacer **36** so that they can be aligned with the two off-axis lumens **26** and **28** in the tip section **14**. The compression coils **46** and stiffening tube **22** are sized so that the compression coils **46** fit closely and slidably within the stiffening tube **22**. With this design, the lead wires **30** distribute themselves around the two compression coils **46** without misalligning the coils.

The compression coils **46** are secured within the catheter body **12** with polyurethane glue or the like. Each compression coil **46** is anchored at its proximal end to the proximal end of the stiffening tube **22** in the catheter body **12** by a glue joint (not shown). When a stiffening tube **22** is not used, each compression coil is anchored directly to the outer wall **20** of the catheter body **12**.

The distal end of each compression coil **46** is anchored to the distal end of the stiffening tube **22** in the catheter body **12** by a glue joint **52**, or directly to the distal end of the outer wall **20** of the catheter body **12** when no stiffening tube **22** is used. Alternatively, the distal ends of the compression coils **46** may extend into the off-axis lumens **26** and **28** of the tip section **14** and are anchored at their distal ends to the proximal end of the tip section **14** by a glue joint. In the depicted embodiment, where the compression coils **46** are each surrounded by a sheath **48**, care should be taken to insure that the sheath is reliably glued to the compression coil. The lead wires **30** can also be anchored in the glue joint. However, if desired, tunnels in the form of plastic tubing or the like can be provided around the lead wires at the glue joint to permit the lead wires to be slidable within the glue joint.

The glue joints preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body **20** and the central lumen **18**. Such a hole may be formed, for example, by a needle

or the like that punctures the outer wall **20** and the stiffening tube **22** that is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **46** and wicks around the outer circumference to form a glue joint about the entire circumference of each sheath **48** surrounding each compression coil **46**. Care must be taken to insure that glue does not wick over the end of the coil so that the puller wire cannot slide within the coil.

Within the off-axis lumens **26** and **28**, each puller wire **32** is surrounded by a plastic sheath **42**, preferably made of Teflon®. The plastic sheathes **42** prevent the puller wires **32** from cutting into the wall of the tip section **14** when the tip section is deflected. Each sheath **42** ends near the distal end of each puller wire **32**. Alternatively, each puller wire **32** can be surrounded by a compression coil where the turns are expanded longitudinally, relative to the compression coils extending through the catheter body, such that the surrounding compression coil is both bendable and compressible.

Longitudinal movement of a puller wire **32** relative to the catheter body **12**, which results in deflection of the tip section **14** in the direction of the side of the tip section to which that puller wire is anchored, is accomplished by suitable manipulation of the control handle **16**. A suitable bidirectional control handle for use in the present invention is described in copending Application Serial No. 09/822,087, filed March 30, 2001 and entitled "Steerable Catheter with a Control Handle Having a Pulley Mechanism", the disclosure of which is incorporated herein by reference. Other suitable bidirectional control handles are described in U.S. Patent Nos. 6,123,699, 6,171,277, 6,183,463, and 6,198,974, the disclosures of which are incorporated herein by reference.

Alternatively, the catheter can be unidirectional, having only a single puller wire extending through an off-axis lumen. Examples of suitable unidirectional catheter designs and control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502 and 5,897,529, the disclosures of which are incorporated herein by reference.

The tip section **14** includes a mechanism for enhancing control over the deflection of the tip section. The mechanism comprises one or more stabilizing features extending longitudinally along at least a portion of the length of the tip section **14**. The stabilizing features are positioned generally symmetrically about a diameter **D** of the tip section, where that diameter corresponds to the plane in which the catheter is deflectable. In the case of a bidirectional catheter, that diameter **D** corresponds to the diameter along which both lumens **26** and **28** are positioned. In the case of a unidirectional catheter, the lumen in which the puller wire is anchored lies along the

diameter **D**. The stabilizing features comprising a material that has a higher modulus of elasticity than the plastic that forms the tip section **14**.

The stabilizing features should be generally rigidly in place relative to the tip section **14** so that the stabilizing features cannot shift, longitudinally, radially or circumferentially, relative to the tip section. Preferably the stabilizing features are fixedly attached to the tip section, e.g., by being coextruded with the tip section or by being glued with polyurethane glue or the like. Where the stabilizing features are not fixedly attached to the tip section, they should be confined to regions that are approximately the same size as the stabilizing features so that the stabilizing features do not shift within the regions.

In the embodiment of FIG. 5A, the tip section **14** includes two stabilizing features in the form of rods **54**. The rods **54** are preferably made of metal, but could also be made of a suitable plastic. The rods **54** extend through the outer layer **27** on opposite sides of the tip section **14** so that they are both positioned along a diameter **D**. During manufacturing, the rods **54** are preferably coextruded with the outer layer **27**, although the rods could instead be inserted in small lumens formed in the outer layer. Where the rods **54** are made of metal, preferably the rods are not exposed on the outside of the tip section. The two off-axis lumens **26** and **28** are positioned on opposing sides of the diameter **D**. Longitudinal movement of one of the puller wires **32** results in deflection of the tip section across the diameter **D**.

This arrangement improves the in-plane deflection of the tip section **14** because the less-elastic stabilizing features (e.g., the rods **54**) reduce the tip section's tendency to bend in a direction other than across the diameter along which the stabilizing features are positioned. The stabilizing features also act to increase the lateral tip stability, which results in the user being able to create a greater contact force against the heart tissue. Thus, the catheter exhibits increased ablation stability.

FIG. 5B depicts an alternative embodiment in which the tip section **14** includes two stabilizing features in the form of strips **56**, preferably made of plastic, positioned in the outer layer **27**. The strips **56**, like the rods **54** described above, are provided on opposite sides of the tip section **14** so that they are both positioned along a diameter **D**. Preferably the strips **56** are coextruded with the outer layer **27**. The strips **56** function in a manner similar to the rods **54**. The precise shape of the stabilizing features located in the outer layer **27** is not critical and can vary based on the application.

FIG. 5C depicts another alternative embodiment in which the tip section **14** includes two pie-shaped stabilizing features **58** in the core **24**. Preferably the stabilizing features **58** are coextruded with the core **24**.

It is generally preferred that the stabilizing features be located as far from the axis of the tip section **14** as possible. In the case where the stabilizing features are located within the core, for example, as shown in FIG. 5C, it is preferred that the bulk of the mass of each stabilizing feature be positioned away from the axis.

FIG. 5D depicts yet another alternative embodiment in which the tip section **14** includes a single bar-shaped stabilizing feature **60** positioned in the core **24** along the diameter **D** corresponding to the plane in which the catheter is deflectable. Preferably the stabilizing feature **60** is coextruded with the core **24**. The single stabilizing feature can take any other suitable shape, such as an oval, that meets the criteria set forth above.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.